

# ADDENDUM



Editor's Note: Additions are indicated by Text  
 and deletions by ~~Text~~.

Supreme Court of New Jersey.  
 Robert ROWE, Plaintiff-Respondent,  
 v.  
 HOFFMAN-LA ROCHE, INC., and Roche Labora-  
 tories, a member of the Roche Group, Defen-  
 dants-Appellants,  
 and  
 ABC Corporation (said name being fictitious) and  
 Drs. John Doe 1-10, Defendants.  
 Argued Jan. 3, 2007.  
 Decided March 29, 2007.

**Background:** Michigan consumer brought products liability action against pharmaceutical companies for failing to adequately warn of possible psychological side effects of acne drug. Companies brought motion for summary judgment. The Superior Court, Law Division, Essex County, granted motion and dismissed complaint. Consumer appealed. The Superior Court, Appellate Division, Wecker, J.A.D., 383 N.J.Super. 442, 892 A.2d 694, reversed and remanded. Appeal was permitted.

**Holding:** The Supreme Court, Lefelt, J. (temporarily assigned), held that Michigan, rather than New Jersey, law applied and barred the suit.

Reversed and remanded.

Stern, J. (temporarily assigned), concurred in part and dissented in part and filed opinion joined by Long, J.

West Headnotes

## [1] Action 13 17

### 13 Action

#### 13II Nature and Form

13k17 k. What Law Governs. Most Cited

#### Cases

Courts apply New Jersey choice-of-law rules to law-suits filed there.

## [2] Torts 379 103

### 379 Torts

#### 379I In General

379k103 k. What Law Governs. Most Cited

#### Cases

Two steps are involved in governmental-interests analysis of choice of law in tort suit: (1) determine on an issue-by-issue basis whether a conflict exists between state laws, and (2) if a conflict exists, determine the interest that each state has in resolving the specific issue in dispute.

## [3] Action 13 17

### 13 Action

#### 13II Nature and Form

13k17 k. What Law Governs. Most Cited

#### Cases

If there is no actual conflict, then the choice-of-law question is inconsequential, and the forum state applies its own law to resolve the disputed issue.

## [4] Torts 379 103

### 379 Torts

#### 379I In General

379k103 k. What Law Governs. Most Cited

#### Cases

If a conflict of laws exists in a tort suit, a court must identify the governmental policies underlying the law of each state and determine whether those policies are affected by each state's contacts to the litigation and to the parties; the court must apply the law of the state with the greatest interest in governing the particular issue.

## [5] Torts 379 103

### 379 Torts

#### 379I In General

379k103 k. What Law Governs. Most Cited

#### Cases

If the contacts of a state do not align with the policies relating to the disputed issue, then that state generally will not be found to have the greatest interest in go-

verning the issue, and its law will not apply in tort suit.

## **[6] Products Liability 313A 🔑105**

### **313A Products Liability**

#### **313AI In General**

##### **313Ak105 k. What Law Governs. Most Cited**

#### **Cases**

(Formerly 313Ak3)

## **Products Liability 313A 🔑225**

### **313A Products Liability**

#### **313AIII Particular Products**

##### **313Ak223 Health Care and Medical Products**

##### **313Ak225 k. Drugs in General. Most Cited**

#### **Cases**

(Formerly 313Ak3)

Michigan's conclusive presumption that acne drug was not defective since Food and Drug Administration (FDA) had approved labeling, rather than New Jersey's rebuttable presumption of adequate warning, applied to Michigan patient's products liability action against pharmaceutical companies with principal place of business in New Jersey; Michigan's interest in making more prescription drugs generally available to its citizens outweighed New Jersey interest in deterring its corporations from providing inadequate product warnings. M.C.L.A. § 600.2946(5); N.J.S.A. 2A:58C-4.

## **[7] Action 13 🔑17**

### **13 Action**

#### **13II Nature and Form**

##### **13k17 k. What Law Governs. Most Cited**

#### **Cases**

It is the forum state's duty to disregard its own substantive preference in deciding choice of laws.

**\*\*768**Paul W. Schmidt, a member of the District of Columbia bar, argued the cause for appellants (Gibbons, Del Deo, Dolan, Griffinger & Vecchione, attorneys, Newark; Mr. Schmidt, Washington, DC, Michael R. Griffinger, Diane E. Lifton and Kristine V. Ryan, Newark, on the briefs).

Brian J. Molloy, Woodbridge, argued the cause for respondent (Wilentz, Goldman & Spitzer, attorneys; Mr. Molloy and Jeffrey J. Brookner, on the brief).

Ingo W. Sprie, New York City, submitted a brief on behalf of amicus curiae Pharmaceutical Research and Manufacturers of America.

Anita Hotchkiss, Morristown, submitted a joint brief on behalf of amici curiae Product Liability Advisory Council, Inc. and New Jersey Defense Association (Porzio, Bromberg & Newman, Morristown and Norris, McLaughlin & Marcus, Bridgewater, attorneys; Ms. Hotchkiss, **\*\*769**Steven A. Karg, Bridgewater, Kerry J. Roach, Newark, John T. Chester, Morristown, of counsel and on the brief).

Michael G. Donahue, III, Lawrenceville, submitted a brief on behalf of amicus curiae Association of Trial Lawyers of America-New Jersey (Stark & Stark, attorneys).

Edward J. Fanning, Jr., Newark, submitted a brief on behalf of amicus curiae Healthcare Institute of New Jersey (McCarter & English, attorneys; Mr. Fanning and David R. Kott, of counsel; Mr. Fanning, Mr. Kott and Marielena Piriz, on the brief).

Judge LEFELT (temporarily assigned) delivered the opinion of the Court.

**\*617** Plaintiff Robert Rowe, a Michigan resident, filed a complaint in Essex County against two New Jersey pharmaceutical **\*618** manufacturers, defendants Hoffmann-La Roche, Inc. and Roche Laboratories, Inc. Rowe alleged that the manufacturers failed to warn adequately about the health risks associated with Accutane, a drug manufactured by defendants and approved in 1982 by the United States Food and Drug Administration (FDA) to treat recalcitrant nodular acne. Under Michigan law, the FDA approval results in a conclusive determination that the health risk warnings issued by defendants regarding the drug were adequate. Mich. Comp. Laws § 600.2946(5)(2006). New Jersey law, however, considers the FDA approval to have created only a rebuttable presumption of adequacy. N.J.S.A. 2A:58C-4. Thus, plaintiff's suit is viable in New Jersey but precluded in Michigan. After comparing Michigan's and this State's governmental interests in resolving the adequacy-to-warn issue, we conclude that Michigan's interest is paramount and its conclusive presumption applies. Consequently, we reverse the contrary Appellate Division decision, Rowe v. Hoffmann-La Roche Inc., 383 N.J.Super. 442, 892 A.2d 694

([App.Div.2006](#)), and reinstate the trial court's decision dismissing Rowe's complaint.

I.

The facts and procedural history pertaining to this dispute are relatively uncomplicated. Hoffmann-La Roche is a New Jersey corporation, and while the record does not reveal Roche Laboratories' state of incorporation, both companies have their principal place of business in Nutley, New Jersey. Hoffman-La Roche manufactures, labels, and packages Accutane in Nutley, and Roche Laboratories markets, sells, and distributes the drug also from Nutley. While some production and marketing efforts occurred outside New Jersey, almost all of the manufacturing and sales activities by the two companies (hereinafter Hoffmann), including Accutane-related communications with the FDA, took place in or emanated from New Jersey.

Robert Rowe has lived in Michigan all of his life. When Rowe was sixteen years old, in February 1997, a Michigan physician prescribed [Accutane](#) to treat his recalcitrant acne. A Michigan pharmacist filled Rowe's prescription, and he used the medicine in Michigan for about three months until May 1997. Approximately \*619 three months after he discontinued his use of [Accutane](#), in August 1997, Rowe became depressed and contemplated suicide. In September 1997, Rowe was arrested after crashing a car into a house during an apparent suicide attempt. Thereafter, Rowe sought psychiatric treatment in Michigan and Ohio.

In March 2001, Rowe brought suit against Hoffmann in Essex County, New Jersey. He alleged that [Accutane](#) caused him to become severely depressed and suicidal\*\*770 and that Hoffmann failed to warn him adequately about these risks. He also claimed Hoffmann did not adequately test [Accutane](#), and that Hoffmann was aware of the drug's potential adverse psychological effects but failed to advise the FDA of those effects.

After denying Rowe's allegations, Hoffmann moved for summary judgment, seeking dismissal of the lawsuit, contending that Michigan law governed. The trial court, relying on the Appellate Division's decision in [Deemer v. Silk City Textile Machinery Co.](#), 193 N.J.Super. 643, 475 A.2d 648 (App.Div.1984), con-

cluded that between New Jersey and Michigan, Michigan had the strongest governmental interest in applying its statute to the failure-to-warn issue, and dismissed Rowe's complaint. A divided panel of the Appellate Division reversed. [Rowe, supra](#), 383 N.J.Super. at 442, 892 A.2d 694.

The Appellate Division majority disagreed with the trial court and held that New Jersey had the strongest interest in applying its law to Rowe's failure-to-warn claim. [Id.](#) at 466, 892 A.2d 694. The majority recognized that "the cited conduct of [Hoffmann] with respect to the [Accutane](#) warning occurred largely in New Jersey." [Id.](#) at 456, 892 A.2d 694. Relying on this Court's opinion in [Gantes v. Kason Corp.](#), 145 N.J. 478, 679 A.2d 106 (1996), the majority recognized and weighed our strong interest in deterring the manufacture of unsafe products within its borders. [Rowe, supra](#), 383 N.J.Super. at 458-59, 892 A.2d 694.

The majority found our interest outweighed Michigan's because Michigan's purpose in enacting the provision at issue may have been to protect only Michigan businesses, an interest not implicated\*620 here because Hoffmann is not a Michigan drug manufacturer. [Id.](#) at 460-61, 892 A.2d 694. The majority further concluded that no evidence existed in the record to support a finding that Michigan enacted its statute in response to a shortage of prescription drugs in that state. [Ibid.](#) Even if Michigan intended to create a "more hospitable commercial atmosphere, to encourage drug manufacturers to locate in that state," the majority believed that application of New Jersey's statute would foster that purpose. [Id.](#) at 461 n. 5, 892 A.2d 694.

Judge Wefing dissented. She noted that, contrary to the majority's assertion, the policy behind Michigan's statute was not limited to the protection of Michigan businesses. [Id.](#) at 467, 892 A.2d 694. The judge found that "the actions of the Michigan Legislature sprang from concern about the effect of litigation on the availability and cost of prescription medications for its citizens." [Id.](#) at 469, 892 A.2d 694. The judge also questioned the majority's analysis of New Jersey's interest, concluding that this State had no interest in compensating Rowe because Rowe was a Michigan resident. [Ibid.](#) Finally, Judge Wefing was concerned that by applying New Jersey law to this issue, New Jersey courts would become a haven for out-of-state litigants who reside in states that protect pharma-

ceutical manufacturers. [Id. at 470, 892 A.2d 694.](#)

## II.

The parties' arguments on appeal mirror the two Appellate Division opinions, with Rowe advancing the majority's views and Hoffmann siding with Judge Wefing.

Although the Association of Trial Lawyers of America-New Jersey (ATLA) supports the Appellate Division majority's opinion, all of the other amici curiae, Product Liability Advisory Council, Inc., Healthcare Institute of New Jersey, New Jersey Defense Association, and the Pharmaceutical\*\*771 Research and Manufacturers of America, contend the majority erred by applying New Jersey law to this dispute. ATLA and the Healthcare Institute also take conflicting positions regarding the decision's impact on New Jersey's\*621 economy. The Product Liability Advisory Council and the New Jersey Defense Association request that this Court take judicial notice of their contention that since 1996, over ninety percent of mass-tort claims against New Jersey pharmaceutical companies in New Jersey courts have been brought by non-New Jersey residents. The Advisory Council and the Defense Association conclude by arguing that "New Jersey's strong interest in discouraging ... forum shopping and the associated expense that many thousands of out-of-state residents place on this state's courts and its taxpayers should therefore be accorded great weight."

## III.

[1] When law suits are filed in New Jersey, we apply our choice-of-law rules. [Erny v. Estate of Merola, 171 N.J. 86, 94, 792 A.2d 1208 \(2002\)](#). In tort suits, such as this one, we no longer mechanistically apply the law of the place of wrong. [Fu v. Fu, 160 N.J. 108, 118, 733 A.2d 1133 \(1999\)](#). Instead, we currently subscribe to the more flexible governmental-interests analysis. [Erny, supra, 171 N.J. at 94, 792 A.2d 1208](#). Compare [Clement v. Atl. Cas. Ins. Co., 13 N.J. 439, 442, 100 A.2d 273 \(1953\)](#) (utilizing the place of wrong test) with [Mellk v. Sarahson, 49 N.J. 226, 234-35, 229 A.2d 625 \(1967\)](#) (utilizing interest analysis).

[2][3] In applying the governmental-interests analysis, two steps are involved. [Erny, supra, 171 N.J. at 100-01, 792 A.2d 1208](#). "The first step in the analysis

is to determine whether a conflict exists between the laws of the interested states. Any such conflict is to be determined on an issue-by-issue basis." [Veazey v. Doremus, 103 N.J. 244, 248, 510 A.2d 1187 \(1986\)](#). If there is no actual conflict, then the choice-of-law question is inconsequential, and the forum state applies its own law to resolve the disputed issue.

[4] If there is an actual conflict, the second step "seeks to determine the interest that each state has in resolving the specific \*622 issue in dispute." [Gantes, supra, 145 N.J. at 485, 679 A.2d 106](#). The Court must "identify the governmental policies underlying the law of each state" and determine whether "those policies are affected by each state's contacts to the litigation and to the parties." [Veazey, supra, 103 N.J. at 248, 510 A.2d 1187](#). We must apply the law of "the state with the greatest interest in governing the particular issue." [Ibid.](#)

All parties agree that this case presents an actual conflict. Michigan provides:

In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the [FDA], and the drug and its labeling were in compliance with the [FDA]'s approval at the time the drug left the control of the manufacturer or seller.

[\[Mich. Comp. Laws § 600.2946\(5\).\]](#)

In contrast, New Jersey's law provides:

In any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction....

\*\*772 If the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the [FDA], a rebuttable presumption shall arise that the warning or instruction is adequate.

[\[N.J.S.A. 2A:58C-4.\]](#)

The Michigan statute thus creates a conclusive presumption that the drug is not defective if the drug and its labeling were approved by the FDA, while New Jersey's statute creates a rebuttable presumption that a drug warning is adequate if it was approved by the FDA. Compare [Zammit v. Shire US, Inc.](#), 415 F.Supp.2d 760, 764-65 (E.D.Mich.2006) (holding that defendant drug manufacturer was not liable to plaintiff for failure to warn under [section 600.2946\(5\)](#) because drug was approved by the FDA), with [Feldman v. Lederle Labs.](#), 125 N.J. 117, 156-57, 592 A.2d 1176 (1991) (recognizing that the presumption is only rebuttable, and not conclusive).

[5] Because an actual conflict exists between New Jersey and Michigan on the very issue in dispute-Rowe's failure-to-warn \*623 claim against Hoffmann-we must advance to the next step of the governmental interest analysis. That requires that we identify the policies underlying the New Jersey and Michigan statutes and determine whether those policies are affected by the "state[s]" contacts to the litigation and the parties." [Fu, supra](#), 160 N.J. at 119, 733 A.2d 1133 (quoting [Veazey, supra](#), 103 N.J. at 248, 510 A.2d 1187); see also Earl M. Maltz, *Do Modern Theories of Conflict of Laws Work? The New Jersey Experience*, 36 Rutgers L.J. 527 (2005). If the contacts of a state do not "align with the policies" relating to the disputed issue, then that state generally will not be found to have the greatest interest in governing the issue. [Erny, supra](#), 171 N.J. at 101, 792 A.2d 1208 (citing [Veazey, supra](#), 103 N.J. at 248, 510 A.2d 1187). So, for example, if a particular policy is designed to enhance a specific group and that group is neither a party to nor potentially affected by the litigation, then that state's interest is not aligned with its policy and it would be unlikely that that state would have the strongest governmental interest in deciding the issue. See [White v. Smith](#), 398 F.Supp. 130, 134 (D.N.J.1975) ("If a strong state policy or interest will be neither fostered by applying that state's law, nor frustrated by the failure to apply it, it is highly unlikely that that state has any interest whatsoever in blanketing that particular issue with its law.").

#### IV.

[6] It is in the weighing of each state's interests in deciding the adequacy-of-warning issue that we part

company with the Appellate Division majority. In our view, the majority of the panel overvalued New Jersey's interest and undervalued Michigan's.

The New Jersey statute at issue, [N.J.S.A. 2A:58C-4](#), was enacted in 1987 as part of the New Jersey Products Liability Act (NJPLA), [N.J.S.A. 2A:58C-1](#) to -7, in order to re-balance the law "in favor of manufacturers." William A. Dreier, et al., *N.J. Prods. Liab. & Toxic Torts Law* at 15:4 (2007). "The Legislature intended\*624 for the Act to limit the liability of manufacturers so as to 'balance[ ] the interests of the public and the individual with a view towards economic reality.' " [Zaza v. Marquess & Nell, Inc.](#), 144 N.J. 34, 47-48, 675 A.2d 620 (1996) (quoting [Shackil v. Lederle Labs.](#), 116 N.J. 155, 188, 561 A.2d 511 (1989)). Furthermore, at least in part, the NJPLA was intended "to establish clear rules with respect to specific matters as to which the decisions of the courts in New Jersey have created uncertainty." Senate Judiciary Committee, *Statement to Senate \*\*773 Committee Substitute for S.B. No. 2805*, at 1 (Mar. 23, 1987).

The legislative history of the NJPLA does not specifically address why the Legislature created only a rebuttable presumption of adequacy for FDA approval of prescription drug warnings. Rowe argues, however, that New Jersey has an interest in applying its rebuttable presumption of adequacy here because Hoffmann is a New Jersey company that has manufactured [Accutane](#) in New Jersey. Rowe contends his argument is supported by this Court's decision in [Gantes, supra](#), 145 N.J. 478, 679 A.2d 106, a contention we now address.

In [Gantes](#), the representative of a deceased Georgia resident filed a products liability action against a New Jersey manufacturer in New Jersey. 145 N.J. at 483-84, 679 A.2d 106. The plaintiff alleged that the decedent was killed when a shaker machine, manufactured by the defendant, struck the decedent in the head at the decedent's place of employment in Georgia. *Id.* at 482, 679 A.2d 106. The defendant had manufactured the shaker machine in New Jersey thirteen years before the accident. *Id.* at 481, 679 A.2d 106. Under Georgia law, the plaintiff's lawsuit was barred because Georgia had a statute of repose that prohibited products liability actions being brought more than ten years after the original sale of the product. *Id.* at 485, 679 A.2d 106. New Jersey law,



however, contained no statute of repose. Under New Jersey law, the plaintiff was permitted to proceed with the lawsuit because the plaintiff filed suit within New Jersey's two-year statute of limitation. *Ibid.* The issue before the Court was \*625 whether the Georgia statute of repose or the New Jersey statute of limitation applied to the products liability action.

This Court held that New Jersey's statute of limitation, not Georgia's statute of repose applied, *id.* at 497-98, 679 A.2d 106, reasoning that New Jersey "has a strong interest in encouraging the manufacture and distribution of safe products ... [and] deterring the manufacture and distribution of unsafe products." *Id.* at 490, 679 A.2d 106. In *Gantes*, although plaintiff was not a New Jersey resident and the injury did not occur in New Jersey, our strong interest in deterring the manufacture of unsafe products in this State was directly furthered because plaintiff's suit was timely and not otherwise barred. Georgia's interest was not frustrated by the application of our statute of limitations because its statute-of-repose was designed to stabilize Georgia's insurance industry and to keep stale claims out of its courts. *Id.* at 493, 679 A.2d 106.

New Jersey's interest in allowing Rowe's suit to proceed is not as strong as our interest was in *Gantes*. Rowe argues that unlike Michigan's conclusive presumption, our law provides only a rebuttable presumption of adequacy. However, the law does create a presumption of adequacy rather than simply recognizing FDA approval as one factor to be considered in determining the adequacy of the warnings. See *Rowe*, 383 N.J.Super. at 465 n. 8, 892 A.2d 694 (noting that at least nine states either establish a rebuttable presumption of adequacy "or simply allow FDA-approval as a factor to be considered in determining the adequacy of such warning").

The NJPLA impliedly accepts that the presumption of adequacy will not be rebutted in all cases. It accepts FDA regulation as sufficient, at least in part, to deter New Jersey pharmaceutical companies from manufacturing unsafe prescription drugs. The FDA requires that the labeling accompanying a prescription drug "describe serious adverse reactions and potential safety hazards" and that the labeling "be revised to include a warning as soon as there is reasonable evidence of an \*\*774 association of a serious hazard with a drug." 21 C.F.R. § 201.00(e). If any labeling "is false or \*626 misleading in any particular and was not

corrected within a reasonable time," among other enforcement options, the FDA may withdraw approval for the drug. 21 U.S.C.A. § 355(e). As this Court has stated, "absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive" of a failure-to-warn claim. *Perez v. Wyeth Labs., Inc.*, 161 N.J. 1, 25, 734 A.2d 1245 (1999).

The Legislature also provides in the NJPLA that FDA approval of prescription drugs conclusively prohibits an award of punitive damages in products liability actions. See *N.J.S.A. 2A:58C-5*. This provision, along with the rebuttable-presumption contained in *N.J.S.A. 2A:58C-4*, cede to FDA regulation some of this State's interest in policing local pharmaceutical manufacturers, thereby reducing New Jersey's interest in applying its law to this case.

The predominant object of the law is not to encourage tort recoveries by plaintiffs, whether New Jersey citizens or not, in order to deter this State's drug manufacturers. On the contrary, the law limits the liability of manufacturers of FDA-approved products by reducing the burden placed on them by product liability litigation. The Legislature carefully balanced the need to protect individuals against the need to protect an industry with a significant relationship to our economy and public health. New Jersey's interest in applying its law to Rowe's failure-to-warn issue, when properly discerned, is not antithetical to Michigan's interest but substantially congruent.

The relevant Michigan statute, *Mich. Comp. Laws § 600.2946(5)*, was enacted by the Michigan Legislature in 1996 as part of a comprehensive reform of Michigan's tort law. *Senate Fiscal Agency Bill Analysis to S.B. 344 & H.B. 4508*, at 1 (Jan. 11, 1996). The Michigan Legislature's express purpose was to immunize pharmaceutical companies that market FDA-approved prescription drugs from liability in a products liability suit. See *Mich. Comp. Laws § 600.2946(5)*.

\*627 Hoffmann additionally argues that Michigan's interest in enacting this law was to make prescription drugs more available to Michigan residents. The Appellate Division majority found this interest to be unsupported by the record. *Rowe, supra*, 383 N.J.Super. at 461, 892 A.2d 694. Contrary to that

finding, however, Michigan's interest in making prescription drugs more available to its residents is supported by the legislative history of the law. Commenting on [Section 600.2946\(5\)](#), its proponents stated that “[d]rug companies spend large sums of money and expend enormous energy getting approval for their products. Many valuable products never reach the market or are withdrawn because of successful lawsuits (or the threat of future lawsuits) even though there is no medical evidence that they are harmful.” *House Legislative Analysis Section to S.B. 344*, at 9 (June 8, 1995). Supporters in the Michigan State Senate recognized that “[c]onsumers ... suffer when they are denied new products that would increase public safety or improve their quality of life.... [P]roduct liability litigation ... has added substantially to the cost and unavailability of many goods and services.” *Senate Fiscal Agency Bill Analysis to S.B. 344 & H.B. 4508*, at 10 (Jan. 1, 1996).

Hoffmann's claim also is supported by case law. For example, [Garcia v. Wyeth-Ayerst Labs.](#), 385 F.3d 961 (6th Cir.2004), considered a constitutional challenge to [Section 600.2946\(5\)](#). Citing legislative history, the court noted that “it appears that \*775 the Michigan legislature was concerned that unlimited liability for drug manufacturers ... could add substantially to the cost and unavailability of many drugs.” *Id.* at 967; see also Elissa Levy, Note, *The Health Act's FDA Defense to Punitive Damages: A Gift to Drug Makers or to the Public*, 74 *Fordham L.Rev.* 2425, 2440 n. 101 (2006) (citing [Henderson v. Merck & Co.](#), No. 04-CV-05987-LDD, 2005 WL 2600220, at \*7 (E.D.Pa. Oct. 11, 2005) (“Michigan has a strong interest in applying its law to ensure that Michigan residents ... are not burdened with excessively high payments for prescription drugs, ... even if that means immunizing non-resident pharmaceutical companies who do business in Michigan.”)).

\*628 The Appellate Division majority also believed that Michigan's interest in enacting [Section 600.2946\(5\)](#) “may have been to protect Michigan businesses.” [Rowe, supra](#), 383 N.J.Super. at 460, 892 A.2d 694. In support of this finding, it cited [Ammend v. Biopart, Inc.](#), 322 F.Supp.2d 848 (W.D.Mich.2004), which held that [Section 600.2946\(5\)](#)'s conclusive presumption applied to a products liability claim against a Michigan manufacturer. *Id.* at 876. According to the panel's majority, the [Ammend](#) court recognized that [Section 600.2946\(5\)](#)'s “core purpose” was

to regulate Michigan drug manufacturers.

That interpretation of [Ammend](#) is too broad. As Judge Wefing noted in her dissent, the Michigan Legislature had “a wider concern than a parochial desire to protect local pharmaceutical manufacturers.” [Rowe, supra](#), 383 N.J.Super. at 468, 892 A.2d 694 (Wefing, J., dissenting). The court in [Ammend](#) merely recognized that one of the Michigan Legislature's purposes in enacting [Section 600.2946\(5\)](#) was to regulate Michigan manufacturers. [Ammend, supra](#), 322 F.Supp.2d at 876. The court neither discussed any of the other Michigan Legislature's policy concerns, such as the desire to increase access to affordable prescription drugs for Michigan residents, nor concluded that the regulation of Michigan manufacturers was the exclusive purpose of [Section 600.2946\(5\)](#).

Michigan “was concerned that unlimited liability for drug manufacturers would threaten the financial viability of many enterprises and could add substantially to the cost and unavailability of many drugs.” [Garcia, supra](#), 385 F.3d at 967. This concern is echoed by others. For example, speaking of vaccines, several commentators have noted that “the prospect of multi-million dollar verdicts instead [of encouraging safer vaccines] induced manufacturers to abandon the vaccine market altogether.” W. Kip Viscusi, et al. *The Effect of Products Liability Litigation on Innovation: Detering Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 *Seton Hall L.Rev.* 1437, 1470 (1994); see also [Shackil v. Lederle Labs.](#), 116 N.J. 155, 181, 561 A.2d 511 (1989) (“The overriding public policy of \*629 encouraging the development of necessary drugs is not unfamiliar to products-liability law.”).

V.

This case presents a true conflict of laws because both New Jersey and Michigan have interests that would be furthered by applying their respective statutes to Rowe's failure-to-warn claim against Hoffmann. After properly discerning and weighing the respective policies of New Jersey and Michigan, however, we reach a result different from the Appellate Division majority. In this instance, New Jersey's interest is limited and outweighed by Michigan's interest in making more prescription drugs generally available to its citizens.



**\*\*776**[7] Furthermore, comity precludes closing our eyes to Michigan's interest. Even if we were to question the effectiveness of the Michigan statute in accomplishing its goal, "it is the forum state's duty to disregard its own substantive preference." *Fu, supra*, 160 N.J. at 130-31, 733 A.2d 1133 (quoting *O'Connor v. Busch Gardens*, 255 N.J. Super. 545, 549, 605 A.2d 773 (App.Div.1992)). The question is not whether Michigan or New Jersey passed the better law; that is a normative judgment best suited for the legislative process. Our inquiry is limited to which state has the greatest interest in applying its law to Rowe's failure-to-warn claim.

To allow a life-long Michigan resident who received an FDA-approved drug in Michigan and alleges injuries sustained in Michigan to by-pass his own state's law and obtain compensation for his injuries in this State's courts completely undercuts Michigan's interests, while overvaluing our true interest in this litigation.

In this instance, where the challenged drug was approved by the FDA and suit was brought by an out-of-state plaintiff who has no cause of action in his home state, this State's interest in ensuring that our corporations are deterred from producing unsafe products—which was determinative in *Gantes* and however **\*630** weighty in other contexts—is not paramount. Our interest in deterring local manufacturing corporations from providing inadequate product warnings, within the context of an FDA approved drug, must yield to Michigan's interest.<sup>FN1</sup>

<sup>FN1</sup>. We note that our dissenting colleagues suggest that we withhold issuing this decision for an unspecified period to determine whether a bill, which has passed the Michigan House, becomes law. The Bill, H.B. 4044-4045, 94th Leg., Reg. Sess. (Mich.2007), if adopted by Michigan would repeal *Mich. Comp. Laws* § 600.2946(5), and enact a rebuttable presumption that products are safe if they are subject to, and comply with, pertinent government safety standards. Because of the uncertain duration and predictability of legislative activity, however, we decline to accede to the dissenters' suggestion. We are confident that should the Bill become law, the parties in this case will take whatever actions they believe are warranted.

## VI.

The judgment of the Appellate Division is reversed and the case is remanded to the Law Division for reinstatement of the trial court's order dismissing the lawsuit.

Judge *STERN* (temporarily assigned), dissenting. I travel the same path as the majority but reach a different destination. Thus, although I fully join in Points I, II and III of the majority opinion, I respectfully dissent from the result reached in Points IV and V.

As the majority develops, under the governmental-interest analysis, which defendants acknowledge to be the controlling test for evaluation of the issue before us,<sup>FN1</sup> we must determine whether an actual conflict of laws exists as to a particular issue, and, if so, we must then "identify the governmental policies underlying the law of each state" and determine "how those policies are affected by each state's contacts to the litigation and to the parties." *Veazey v. Doremus*, 103 N.J. 244, 248, 510 A.2d 1187 (1986). After **\*631** performing that balance, we must apply the law "of the state with the greatest interest in governing the particular issue." *Ibid*.

<sup>FN1</sup>. Whether the result would be different under another test or analysis need not be considered in this case. See Earl M. Maltz, *Do Modern Theories of Conflict of Laws Work? The New Jersey Experience*, 36 *Rutgers L.J.* 527, 534-48 (2005).

**\*\*777** I agree with the majority that "there is an actual conflict between the laws of the respective states." *Gantes v. Kason Corp.*, 145 N.J. 478, 484, 679 A.2d 106 (1996) (citing *Veazey, supra*, 103 N.J. at 248, 510 A.2d 1187). As a result, we must inquire as to "the interest that each state has in resolving the specific issue in dispute." *Id.* at 485, 679 A.2d 106. This is done by "identify[ing] the governmental policies underlying the law of each state and how those policies are affected by each state's contacts to the litigation and the parties." *Ibid.* (quoting *Veazey, supra*, 103 N.J. at 248, 510 A.2d 1187). In that respect, "[i]f a state's contacts are not related to the policies underlying its law, then the state does not possess an interest in having its law apply." *Veazey, supra*, 103 N.J. at 248, 510 A.2d 1187. Finally, New Jersey's interest "must be

compared and weighed against any governmental interest” of the other state “in light of [that state’s] contacts with the litigation and the parties.” *Gantes*, [supra](#), 145 N.J. at 493, 679 A.2d 106.

As developed by the majority, the *Accutane* involved in this case was prescribed in Michigan and then taken there by plaintiff, a Michigan resident. However, it was manufactured in, and distributed from, New Jersey, and the very compliance with Federal Food and Drug Administration (“FDA”) processes, which gives rise to an immunity in Michigan, was conducted and completed in New Jersey. Therefore, both states have significant interests worthy of protection: New Jersey, the situs of the manufacturer, in governing its manufacturers for the protection of consumers, and Michigan, where the drug was prescribed and consumed, in promoting the availability of medication at reasonable prices. Moreover, both states also have an interest in considering the impact of litigation on employers and workers as well as the local economy, resulting in Michigan legislation and the New Jersey Products Liability Act, [N.J.S.A. 2A:58C-1](#) to -11.<sup>FN2</sup>

<sup>FN2</sup>. For purposes of this opinion, I assume the reasons behind the Michigan legislation are as broad as stated by the Appellate Division dissent. See *Rowe v. Hoffmann-La Roche Inc.*, 383 N.J.Super. 442, 467-70, 892 A.2d 694 (App.Div.2006) (Wefing, J., dissenting).

\*632 As also fully developed by the majority, *Gantes*, [supra](#), involved a New Jersey products liability action against a New Jersey manufacturer filed on behalf of a decedent killed in Georgia “when she was struck in the head by a moving part of a shaker machine.” 145 N.J. at 482, 679 A.2d 106. The New Jersey courts assumed, for purposes of summary judgment, “that defendant manufactured the machine in New Jersey.” *Ibid*. Under Georgia law, the plaintiff’s lawsuit was barred by a statute of repose prohibiting commencement of products liability actions more than ten years after the original sale of the product. *Id.* at 485, 679 A.2d 106. Under New Jersey law, the suit was subject only to our two-year statute of limitations, [N.J.S.A. 2A:14-2](#). *Ibid*. The issue involved in *Gantes* was, therefore, whether the Georgia statute of repose or the New Jersey statute of limitations controlled the plaintiff’s ability to commence the action.

The *Gantes* Court held that New Jersey’s statute of limitations, not Georgia’s statute of repose, applied. *Id.* at 498, 679 A.2d 106. The majority reasoned that New Jersey has a substantial governmental interest in deterring the manufacture of unsafe products in New Jersey. *Id.* at 489-90, 679 A.2d 106. According to Justice Handler:

This court has recognized generally that a purpose of the tort laws is to encourage reasonable conduct, and, conversely, to discourage conduct that creates an unreasonable risk of injury to \*\*778 others. That deterrent goal of the tort laws is effectuated through the recognition of a duty to exercise reasonable care and the imposition of liability for the breach of such a duty. We note also that Georgia has recognized that “courts are concerned not only with compensation of the victims but with admonition of the wrongdoer” and that the “‘prophylactic’ fact of preventing future harm has been quite important in the field of torts.”

The interest in deterrence has been recognized as a relevant factor to be considered in choice-of-law decisions.

The goal of deterrence, acknowledged generally to be part of tort law, is especially important in the field of products-liability law. In *Fischer v. Johns-Manville Corp.*, 193 N.J.Super. 113, 124], 472 A.2d 577] (1984), *aff’d*, 103 N.J. 643], 512 A.2d 466] (1986), the Appellate Division noted that since \*633 *Henningsen v. Bloomfield Motors, Inc.*, 32 N.J. 358], 161 A.2d 69] (1960), this State’s judiciary has been “in the vanguard of the development of a responsive and progressive products liability law” and “has led the country in its ideological commitment to the protection of consumers and concomitant consequence of inducing those who place products into the stream of commerce to act with social responsibility.” Judge Pressler observed in her dissent below: “the development of [products liability law in New Jersey] and the consequent imposition of strict liability on manufacturers has been a powerful force—perhaps the most powerful force—in effecting, over the last two and a half decades, product safety and social responsibility by industry.”

We conclude that this State has a strong interest in encouraging the manufacture and distribution of

safe products for the public and, conversely, in deterring the manufacture and distribution of unsafe products within the state. That interest is furthered through the recognition of claims and the imposition of liability based on principles of strict products-liability law.

[ *Id.* at 489-90, 679 A.2d 106 (citations omitted).]

In the context of the statute of limitations issue, the Court also articulated why deterrence is a sufficient reason to hold New Jersey manufacturers under the ambit of New Jersey law:

In light of this State's commitment to protection of the public against the manufacture and distribution of unsafe products and the strong governmental interest in deterrence against such practices, it does not seem "pointless" to apply this State's statute of limitations to resident manufacturers, even if the suit would be barred against foreign manufacturers. The difference in result is grounded in the distinctive policy concerns that each state has in making its domestic manufacturers amenable to suits. A governmental interest based on a policy of deterrence that seeks to discourage domestic manufacturers from the manufacture and distribution of unsafe products through the allowance of a products-liability action is not unnecessarily burdensome nor is it discriminatory or baseless.

[ *Id.* at 491, 679 A.2d 106.]

Thus, although the decedent in *Gantes* was not a New Jersey resident and the injury did not occur in New Jersey, this Court permitted her administrator to proceed with the lawsuit against the New Jersey manufacturer in light of New Jersey's interest in deterring the manufacture and distribution of unsafe products within the State. The very same principle applies in this case directed to the adequacy of the product's warnings.

**\*\*779** I recognize that *Gantes* is distinguishable because, unlike the unregulated defendant in that case, the manufacture and distribution of prescription drugs are extensively regulated by the FDA. However, our Legislature, unlike the Legislature of Michigan, has determined that FDA regulation and approval is not per se **\*634** sufficient to deter pharmaceutical companies from providing inadequate warnings or to preclude lawsuits. Only "a rebuttable presumption

shall arise that the warning or instruction is adequate." *N.J.S.A. 2A:58C-4*.

Although our Legislature has precluded punitive damages by virtue of FDA approvals,<sup>FN3</sup> it has determined not to preclude all actions based on inadequate warnings. See *N.J.S.A. 2A:58C-4*, -5. Therefore, neither the preclusion of punitive damages nor the FDA approval of the warning substantially lessens New Jersey's interest in consumer protection. Unlike Michigan, our Legislature has not completely precluded this type of action. See *Perez v. Wyeth Labs., Inc.*, 161 N.J. 1, 24-25, 734 A.2d 1245 (1999). Accordingly, I believe the *Gantes* approach is warranted and controls the disposition of this case. In fact, it seems to me that our Legislature permits recovery, notwithstanding FDA approvals, in the exceptional circumstances in which the presumption can be overcome, because those situations involve matters in which deterrence is needed the most. Michigan's legitimate interests cannot be said to outweigh the need to deter conduct in this State that our Legislature, as a matter of sound public policy, seeks to prevent.

**FN3.** There is an exception "where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question[ ]...." *N.J.S.A. 2A:58C-5*(c). Michigan has a similar exception to its immunity statute. *Mich. Comp. Laws* § 600.2946(5).

Certainly, as the majority develops, Michigan has significant interests in furthering its legislative design. However, those interests in protecting consumers with respect to prescription costs and availability (and even more broadly with respect to tort reform) are remote and outweighed in a New Jersey forum when the Michigan resident brings his or her suit in New Jersey against a New Jersey manufacturer,<sup>FN4</sup> particularly because he or she is **\*635** subject to the "rebuttable" presumption **\*\*780** of the warning or label's adequacy.

**FN4.** It seems clear that Michigan courts would apply Michigan law to this case, resulting in the type of "forum shopping" that attracts plaintiff to New Jersey. See *Sutherland v. Kennington Truck Serv., Ltd.*, 454 Mich. 274, 562 N.W.2d 466, 471-72 (1997).

However, whenever an action is commenced in New Jersey involving a tort or injury that occurred out-of-state, a choice of law analysis is required with respect to the relevant issue that gives rise to an “actual conflict.” As such, “forum shopping” does not necessarily equate with recovery under New Jersey law. Furthermore, the ability to litigate in this State flows from jurisdiction over the defendant and notions of due process, not choice of law principles that will be contested in the course of the litigation. In any event, as stated in Gantes, supra,

[i]n this case, plaintiff does not seek to use New Jersey's court system to litigate a dispute that has only a slight link to New Jersey and where the only plausible reason to select this State is because it is a hospitable forum. This action is materially connected to New Jersey by the fact that the allegedly defective product was manufactured in and then shipped from this State by the defendant-manufacturer.

[ 145 N.J. at 492, 679 A.2d 106.]

Moreover, as the Michigan legislation appears to be unique, see Restatement (Third) of Torts: Product Liability § 6, we need not fear the filing of an onslaught of Accutane product liability cases here.

Accordingly, I would affirm substantially for the reasons expressed in Judge Wecker's opinion for the Appellate Division, as supplemented herein.

Finally, I note there is now pending in the Michigan Senate two bills passed by the Michigan House of Representatives which would enact a rebuttable presumption similar to our own with retroactive applicability. See H.B. 4044-4045, 94th Leg., Reg. Sess. (Mich. 2007). It would seem jurisprudentially sound to wait a reasonable period of time in which to see what happens in the Michigan Senate with respect to the proposed legislation in order to evaluate if the actual conflict is resolved and to avoid a split decision on an issue of such significance as the one now being decided.

Justice LONG joins in this opinion.

**\*636***For reversal and remandment*-Justices La-VECCHIA, WALLACE, RIVERA-SOTO and HOENS and Judge LEFELT-5.

*Concurring in part/dissenting in part*-Justice LONG and Judge STERN-2.  
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